K113211

JAN - 4 2012

510K SUMMARY

ASSAY ONLY TEMPLATE

A.	**510(k) Number**	TBD
B.	**Purpose for Submission**	Addition of reconstituted frozen stability claims
C.	**Measurand**	Controls for Lupus Anticoagulant (LA)
D.	**Type of Test**	Assayed Controls
E.	**Applicant**	Instrumentation Laboratory Co.
F.	**Proprietary & Established Names**	HemosIL LA Positive Control & HemosIL LA Negative Control

G. Regulatory Information

1. *Regulation section:* 21CFR §864.5425, Multipurpose system for in vitro coagulation studies.
2. *Classification:* Class II
3. *Product code:* GGN (Plasma Coagulation Control)
4. *Panel:* 81 Hematology

H. Intended Use

1. *Intended use(s):*

HemosIL LA Negative Control

For use as an LA Negative Quality Control of Lupus Anticoagulant assays (HemosIL dRVVT Screen/dRVVT Confirm, LAC Screen/LAC Confirm; HemosIL Silica Clotting Time) on IL Coagulation systems [ACL TOP® Family; ACL ELITE®/ELITE PRO/8/9/10000; ACL Futura/ACL Advance; ACL Classic (100-7000)].

HemosIL LA Positive Control

For use as an LA Positive Quality Control of Lupus Anticoagulant assays (HemosIL dRVVT Screen/dRVVT Confirm, LAC Screen/LAC Confirm; HemosIL Silica Clotting Time) on IL Coagulation systems [ACL TOP® Family; ACL ELITE®/ELITE PRO/8/9/10000; ACL Futura/ACL Advance; ACL Classic (100-7000)].

2. *Indication(s) for use:*
Same as above

3. *Special conditions for use statement(s):*
For *in-vitro* diagnostic use only. For prescription use.

4. *Special instrument requirements:*
IL Coagulation systems [ACL TOP® Family; ACL ELITE®/ELITE PRO/8/9/10000; ACL Futura/ACL Advance; ACL Classic (100-7000)].

I. Device Description

HemosIL LA Negative Control is a lyophilized preparation using human citrated platelet-poor plasma to make a pooled normal plasma with added buffer. The device consists of ten 1-ml vials of lyophilized controls per package.

HemosIL LA Positive Control is a lyophilized preparation from human donors exhibiting the presence of anti-phospholipid antibodies with added buffer. The device consists of ten 1-ml vials of lyophilized controls per package.

J. Substantial Equivalence Information

1. *Predicate device name(s):* HemosIL LA Negative Control & HemosIL LA Positive Control (self)
2. *Predicate 510(k) number(s):* K110033
3. *Comparison with predicate:*

HemosIL LA Negative Control

The HemosIL LA Negative Control applicant is Substantially Equivalent to its predicate, the HemosIL LA Negative Control that was cleared under K110031, in intended use, fundamental scientific technology, and product composition. **The products are identical in performance in all aspects, except for their reconstituted stability claims.** The applicant has a reconstituted stability of 3 weeks at -20°C in its closed original vial.

HemosIL LA Positive Control

The HemosIL LA Positive Control applicant is Substantially Equivalent to its predicate, the HemosIL LA Positive Control that was cleared under K110031, in intended use, fundamental scientific technology, and product composition. **The products are identical in performance in all aspects, except for their reconstituted stability claims.** The applicant has a reconstituted stability of 3 weeks at -20°C in its closed original vial.

K. Standard/Guidance Document Referenced (if applicable)

Guidance for Industry and FDA Staff - Assayed and Unassayed Quality Control Material (UCM79179), June 7, 2007.

L. Test Principle

LA Positive control is a lyophilized preparation from human donors with anti-phospholipid antibodies with added buffer. LA Negative control consists of a pool of normal human citrated platelet-poor plasma.

The controls are used to assess the precision and accuracy of Lupus Anticoagulant (LA) assays performed on IL Coagulation instrument platforms using HemosIL LA Reagents.

M. Performance Characteristics

1. *Analytical performance*

a. *Precision/Reproducibility:* As established in K110031.

b. *Linearity/assay reportable range:* Not Applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Lyophilized shelf life at 2-8°C: 2 years
After Reconstitution: 24 hours at 2-8°C in its closed original vial.
Reconstituted Frozen Stability: 3 weeks at -20°C in its closed original vial.

On Board Stability:
– 24 hours at 15°C on-board the ACL TOP Family in the original vial,
– 4 hours on the ACL ELITE/ELITE PRO/8/9/10000,
– 4 hours on the ACL Futura/ACL Advance or
– 4 hours on the ACL Classic (100-7000) Systems.

d. *Detection limit: NA*

e. *Analytical specificity:* Not Applicable

f. *Assay cut-off:* Not Applicable

2. *Comparison studies:*
   a. *Method comparison with predicate device*: Not Applicable
   b. *Matrix Comparison:* Not Applicable

3. *Clinical Studies:*
   a. *Clinical Sensitivity:* Not Applicable
   b. *Clinical Specificity:* Not Applicable
   c. *Other clinical supportive data (when a. and b. are not applicable):* NA

4. *Clinical cut-off:* Not Applicable

5. *Expected values/Reference range:* Established in K110031

N. Proposed Labeling

The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

P. Administrative Information

Applicant Contact Information

Name of applicant:	Instrumentation Laboratory Co.
Contact:	Jacqueline Emery, BSEE, Regulatory Affairs Manager
Mailing address:	180 Hartwell Road, Bedford, MA 01730, USA
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Date Prepared	October 27th, 2011

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Instrumentation Laboratory Co.
c/o Jacqueline Emery
Regulatory Affairs Manager
180 Hartwell Road
Bedford, MA 01730

JAN 04 2012

Re: k113211
HemosIL LA Positive Control & HemosIL LA Negative Control
Regulation Number: 21 CFR § 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: Class II
Product Code: GGN, GGC, GIZ
Dated: October 27, 2011
Received: October 31, 2011

Dear Ms. Emery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Leena Philip

For Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K113211

Device Name: HemosIL® LA Positive Control & HemosIL® LA Negative Control

Indications for Use:

HemosIL LA Positive Control is intended for use as an LA Positive Quality Control of Lupus Anticoagulant assays (HemosIL dRVVT Screen/dRVVT Confirm, HemosIL LAC Screen/LAC Confirm and HemosIL Silica Clotting Time Screen and Confirm) on IL Coagulation systems [ACL TOP® Family; ACL ELITE®/ELITE PRO/8/9/10000; ACL Futura/ACL Advance; ACL Classic (100-7000)].

HemosIL LA Negative Control is intended for use as an LA Negative Quality Control of Lupus Anticoagulant assays (HemosIL dRVVT Screen/dRVVT Confirm, HemosIL LAC Screen/LAC Confirm and HemosIL Silica Clotting Time Screen and Confirm) on IL Coagulation systems [ACL TOP® Family; ACL ELITE®/ELITE PRO/8/9/10000; ACL Futura/ACL Advance; ACL Classic (100-7000)].

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113211